

Individual Safety Report



3306356-5-00-01

 RY reporting by health
of a adverse events and
uct problems

Frage Unit Sequence #

CDER

106418

SYSTEM ELECTRONIC 3500 FORM ADAPTATION, Version 1.01, September 1997

A. Patient Information

 Patient Identifier: **ADR** Age at time of event: **1944** Sex: **F** Weight: **62.7** lbs
 Date of birth: **[redacted]** (In confidence)

B. Adverse Event or Product Problem

☒ Adverse Event and/or ☐ Product Problem

Outcomes attributed to adverse event

- ☐ Death ☐ Disability
☐ Life-threatening ☐ Congenital anomaly
☒ Hospitalization - initial ☐ Required intervention to prevent permanent impairment/damage
☐ Hospitalization - prolonged

 3. Date of event (mo/day/yr): **2/3/99** 4. Date of this report (mo/day/yr): **7/6/99**

5. Describe event or problem

A pharmacist reported that a patient began taking an unspecified regimen of acetaminophen on an unspecified date for an unspecified indication. The primary reporter stated that the patient took approximately 4 tablets the day prior to admission. On 2-Feb-99 the patient presented to the emergency care center with JAUNDICE, ELEVATED LIVER ENZYMES (AST>3200, ALT>1600) and an ELEVATED INTERNATIONAL NORMALIZED RATIO (5.96). The primary reporter also stated that the patient received one grain of acetaminophen in the emergency care center prior to diagnosis. The patient was ADMITTED TO THE HOSPITAL, where treatment with acetylcysteine was initiated. The patient's regimen was 7.0 gm x 1, then 3.5 gm orally every 4 hours x 17 doses. The reaction was reported to have resolved.

6. Relevant tests/laboratory data, including dates

 Serum Creatinine: **1.6**
 2/2: INR 5.96, AST >3200, ALT >1600, acetaminophen level 15.4; 2/3: total bilirubin 4.9, INR 4.9

7. Other relevant history, including preexisting medical conditions

 Allergies: **NKDA**
 alcohol abuse; patient presented with right abdominal pain, no oral intake for three days prior to admission, nausea and vomiting for one day prior to admission

C. Suspect Medication(s)

1. Name (give labeled strength, mfr/labeler, if known)

#1 acetaminophen

#2

2. Dose, frequency, route used

#1

#2

3. Therapy Dates (from/to)

#1

#2

4. Diagnosis for use (indication)

#1

#2

5. Event abated after use stopped or dose reduced

#1 Yes

#2

6. Lot # (if known)

#1

#2

7. Exp. date

#1

#2

8. Event reappeared after reintroduction

#1 Unknown

#2

9. NDC # (for product problems only)

10. Concomitant medical products

D. Suspect Medical Device

These fields not used for electronic 3500 reporting at

Internal ADR Event Coding

 Reaction 1: **increased liver enzymes**
 Reaction 2: **abnormal international normalized ratio**
 Reaction 3: **jaundice**
 Reaction 4:
 Reaction 5:

E. Reporter (see confidentiality section on back)

1. Name, address and phone #

ADR Program Coordinator / Drug Information Service

Department of Pharmacy and Drug Information

2. Health Professional

☒ Yes ☐ No

3. Occupation

Pharmacist

4. Also reported to

☐ manufacturer☒ user facility☐ distributor
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box ☐

FDA

 Mail to: MEDWATCH or FAX to:
 5600 Fishers Lane 1-800-FDA-0178
 Rockville MD 20852

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

DSS

JUL 20 1999

REC'D.

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MEDWATCH CTU

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